

**REMARKS**

**A. Status of the Claims**

Claim 21 is amended and claims 1-13 and 26 are cancelled without prejudice to future prosecution. Therefore, after entry of this amendment, claims 14-25 are pending. Support for the amendment to claim 21 is provided, for example, in the specification at page 13, lines 20-32. Therefore, no new matter is entered with this amendment.

**B. Claim Objection**

Claim 26 is objected to as allegedly being of improper dependent form. To expedite prosecution, claim 26 has been cancelled thereby mooting the objection. Withdrawal of the objection is, therefore, respectfully requested.

**C. Claim Rejection Under 35 U.S.C. §112 Second Paragraph - Indefiniteness**

Claim 21 stands rejected as allegedly indefinite for recitation of the phrase "unique within the film layer." In response, Applicant has deleted the phrase "unique within the film layer" and added the phrase "distinguishable from the molecular ligand zone."

Applicant notes that a "chemical environment that is distinguishable from the molecular ligand zone" is explicitly defined in the specification. See Applicant's specification page 13, lines 22-25, stating: "A chemical environment that is distinguishable from the molecular ligand zone, as used herein, means the molecular ligand zone and the additional zone comprise detectably different chemical elements." Likewise a "physical environment that is distinguishable from the molecular ligand zone" is also explicitly defined in the specification. See Applicant's specification at page 13, lines 27-29, stating: "A physical environment that is distinguishable from the molecular ligand zone, as used herein, means the molecular ligand zone and the additional zone comprise detectably different physical elements."

In light of the amendment to claim 21, and the explicit definitions provided in the specification, withdrawal of the rejection under 35 U.S.C. §112 second paragraph is respectfully requested.

**D. Claim Rejection Under 35 U.S.C. §102**

Claims 14-22 and 25 stand rejected as allegedly anticipated by U.S.P. 4,806,312 ("Greenquist"). Applicant respectfully submits that Greenquist fails to anticipate the claimed invention because Greenquist does not disclose a film layer having a molecular ligand that can "diffusibly migrate to the molecular ligand binding site of the molecular analyte to produce a detectable product." See Applicant's claim 14.

The Examiner states that Greenquist's "labeled reagent" is equivalent of Applicant's molecular ligand. See page 5 of the Office Action (stating in part that the "labeled form of a binding partner of the analyte is equivalent to [Applicant's] molecular ligand found on the film layer ...."). The Examiner further states that Greenquist's "labeled reagent" is "permitted to diffuse into and through the reagent layer and into the detection layer ... (col. 6, lines 26-19 *sic* and 37-40)." See page 6 of the Office Action,

Applicant respectfully disagrees that Greenquist's labeled reagent is permitted to diffuse into the detection layer because, according to the cited passage, ***only the labeled reagent/analyte complex is allowed to migrate to the detection layer.*** See Greenquist at Col. 6, lines 29-37, stating in part "then substantially all of the analyte present is brought into direct fluid contact with and specifically bound to the labeled reagent. As a result of the fluidity between the reagent layer and the detection layer, the resulting ***analyte(labeled reagent) complex*** thereby formed is free to migrate within and out of the reagent layer and into the detection layer" (emphasis added).

In fact, Greenquist specifically discloses that ***no labeled reagent is allowed to migrate to the detection layer*** because all of the labeled reagent is either bound to the analyte or bound to the immobilized analyte in the reagent layer: "Any of the labeled reagent which does not become bound to analyte from the test medium is bound to and immobilized by the immobilized analyte in the reagent layer, or where a first and second reagent layer are provided, immobilized in the second reagent layer." See Column 6, line 51-57. Because all of the labeled reagent is either bound to the immobilized analyte, or bound to the analyte thereby forming a labeled reagent/analyte complex, no labeled reagent is allowed to migrate to the detection layer.

In contrast to Greenquist, Applicant's claim 14 specifies that the molecular ligand can "diffusibly migrate to the molecular ligand binding site of the molecular analyte to produce a detectable product." Importantly, Applicant's molecular ligand is not equivalent to Greenquist's "complex." The meaning of the term "molecular ligand" is clearly set forth at page 4 of Applicant's specification: "'Molecular ligand,' as used herein means any non-whole cell compound or molecule of interest for which a diagnostic test is desired." This definition does not include a "complex" between the molecular ligand and the molecular analyte. In fact, the formation of such a complex would destroy the utility of the claimed invention because the complex formation would prevent binding between the molecular ligand and the immobilized molecular analyte, thereby blocking production of a detectable product. Therefore, one skilled in the art, after reading claim 14 and Applicant's disclosure, would immediately recognize that the Applicant's molecular ligand is not equivalent to Greenquist's "complex."

Thus, because Greenquist fails to disclose a film layer having a molecular ligand that can "diffusibly migrate to the molecular ligand binding site of the molecular analyte to produce a detectable product," Applicant respectfully requests withdrawal of the rejection.

#### **E. Claim Rejection Under 35 U.S.C. §103**

Claims 23-24 are rejected as allegedly obvious over Greenquist in view of Bergstrom et al., U.S.P. 5,436,161 ("Bergstrom"), and over Greenquist in view of Nelson et al., 1995 Ana. Chem. ("Nelson"). Applicant respectfully traverse.

Applicant notes that "[t]he examiner bears the burden of establishing a *prima facie* case of obviousness. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993); *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Only if this burden is met does the burden of coming forward with rebuttal arguments or evidence shift to the applicant. *Rijckaert*, 9 F.3d at 1532, 28 USPQ2d at 1956. When the references cited by the examiner fail to establish a *prima facie* case of obviousness, the rejection is improper and will be overturned. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988)." See *In re Deuel*, 51 F.3d 1552, 34 USPQ2d 1210, 1214 (Fed. Cir. 1995). In order to establish a *prima facie* case of obviousness, the rejection must demonstrate that (1) the cited references teach all

the claimed elements; (2) there is a suggestion or motivation in the prior art to modify or combine the reference teachings; and (3) there is a reasonable expectation of success. MPEP § 2143; *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991).

As discussed above, Greenquist fails to teach all the claimed elements because Greenquist does not disclose a film layer having a molecular ligand that can "diffusibly migrate to the molecular ligand binding site of the molecular analyte to produce a detectable product." Both Bergstrom and Nelson fail to cure this defect in Greenquist. Bergstrom is merely cited for disclosing the use of hydrogels in biosensing devices. Nelson is cited for disclosing detection of antigens using MALDI-TOF. Because none of the cited references teach or suggest a film layer having a molecular ligand that can "diffusibly migrate to the molecular ligand binding site of the molecular analyte to produce a detectable product," Applicant respectfully submits that a proper *prima facie* case of obviousness has not been set forth.

Moreover, Greenquist teaches against the use of molecular ligand that interacts with an immobilized molecular analyte to produce a detectable product. As described above, only the labeled reagent/analyte complex is allowed to migrate to Greenquist's detection layer. See Col. 6, lines 29-37. Greenquist discloses that the labeling reagent portion of the labeled reagent/analyte complex, and not the labeling reagent alone, interacts with the immobilized detection reagent thereby generating a reaction product. See Col. 6, line 58-62. Greenquist further discloses that the labeled reagent portion of the complex preferably has only a single analyte binding site. See Col. 6, lines 36-39, stating "the labeled reagent preferably provides only one available binding site for binding of the analyte to the labeled reagent." Of course, that single analyte binding site is occupied by the analyte in the labeled reagent/analyte complex. Thus, in Greenquist's preferred embodiment, the labeling reagent portion of the labeled reagent/analyte complex is not capable of interacting with the immobilized interactive detection reagent in the detection layer through the analyte binding site.

Obviously, if the sole analyte binding region of Applicant's molecular ligand were occupied, interaction with the immobilized molecular analyte would be impossible, thereby preventing the production of a detectable product. Therefore, Greenquist teaches against Applicant's use of molecular ligand that interacts with an immobilized molecular analyte to

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produce a detectable product. Applicant respectfully notes that a "useful general rule" is that references which "teach away cannot serve to create a *prima facie* case of obviousness."

*McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1354 (Fed.Cir. 2001)(citations omitted). "Proceeding contrary to the accepted wisdom...is 'strong evidence of unobviousness.'" *Ruiz v. Foundation Anchoring Systems, Inc.*, 234 F.3d 654, 667 (Fed.Cir. 2000)(citations omitted).

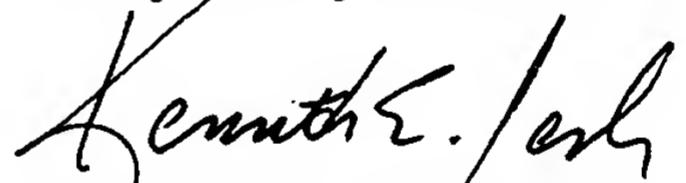
Because the combination of references fail to disclose all the elements of Applicant's claim 14 and teach away from the claimed invention, Applicant respectfully requests withdrawal of the rejection.

### CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 858-350-6100.

Respectfully submitted,



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